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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,797	12/29/2000	Laure Dumoutier	LUD-5543.3 CONT.	5783

24972 7590 10/21/2004

FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/751,797	DUMOUTIER ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *10 August 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *1-19 and 50-52*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☒ Other: APPLICANT'S STATUS REQUEST FILED 10/6/04 IS ACKNOWLEDGED

Phillip Gambel
Primary Examiner 10/14/04
Art Unit: 1644
TECH CENTER 1600

Continuation of 2. NOTE: newly added claims recited limitations, including SEQ ID NOS. 9 and 29 as well as the sizeof the molecule, no previously claimed .

Continuation of 5. does NOT place the application in condition for allowance because: of the reasons of record.
Again, applicant asserts that the claimed molecules are defined by the hybridization conditions which perform the recited function and tha it is the burden that the molecules which fall within the claimed scope would not function as claimed or that undue experimentation is required to identify such molecules. Applicant asserts that the issue is whether the examiner can show that there are molecules which hybridize to the reference and do not activate STAT3. Applicant further poses two questions concerning the non-prior art publications wit respect to hybridization conditions and STAT3 stimulation. However as pointed out previously and in contrast to applicant's assertions and applicant's framing of the issues, neither the specification nor the prior art provides a sufficient structural basis for the recited activity of the encoded protein. Without such sufficient guidance, predicting the structure that defines T cell inducible factors other than those IL-TIF/IL-21 encoded by SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 24 and SEQ ID NO: 25, and which possesses the claimed biological activities of stimulating STAT activation or acute phase production (other than an T cell inducible factors encoded by nucleic acid molecul consisting of SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 24 and SEQ ID NO: 25), is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991) at 18 USPQ2d 1026-1027 and Ex parte Forman, 230 USPQ 546 (BPAI 1986). In re Fisher, 166 USPQ 19, 24 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Therefore, there is insufficient evidence of record to show that one skilled in the art would be able to practice the scope of the claimed invention as claimed without an undue amount of experimentation. While applicant relies upon hybridization conditions and a downstream STAT3 activation of cells. The signal transducers and activators of transcription (STATs) are a family of transcription factors which were originally identified on the basis of their ability to tranduce a signal from a cellular receptor into the nucleus and modulate the transcription of specific genes. STATs including the claimed STAT3 are not limited to T cell inducible factors. Also, STATs mediate regulation of gene transcription through various mechanisms in a variety of cells resulting in a number of endpoints. The specification describes assays for determining whether a given nucleic acid molecule encodes a T cell inducible factor which is a protein which activates STAT3 that might work, this description without more precise guidelines amount to little more that a starting point, a direction for further research. The specification provides for a plan or an invitation for those of skill in the art to experiment practicing the claimed invention but does not provide sufficient guidance or specificity as to how to execute that plan. It provides a starting point from which one of skill in the art can perform further research in order to practice the claimed invention, but this is not adequate to constitute enablement in that will enable an person skilled in the art to make and use the invention as broadly claimed.

Applicant states that Ebner speaks for itself. All the examiner was requesting is for applicant to clarify the scope or metes and bound of IL-22 molecules as claimed herein and as disclosed in the art.